

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

ACTONEL PRODUCTS LIABILITY LITIGATION

This Document Relates To:

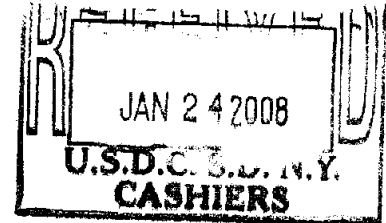
JOYCE LUETTICKE

PLAINTIFF,

-vs.-

PROCTER & GAMBLE PHARMACEUTICALS,
INC., and AVENTIS PHARMACEUTICALS, INC.

DEFENDANTS.



1:06-MD-1789 (JFK)

08 CV 0889
Cause No.

**PLAINTIFF'S ORIGINAL PERSONAL INJURY COMPLAINT
AND DEMAND FOR JURY TRIAL**

COMES NOW Plaintiff Joyce Luetticke, and for her Original Personal Injury Complaint and Demand for Jury Trial against Defendants Procter & Gamble Pharmaceuticals, Inc. (hereinafter "P&G") and Aventis Pharmaceuticals, Inc. (hereinafter "Aventis"), alleges and avers as follows:

PRELIMINARY STATEMENT

1. This is a proceeding brought by Plaintiff seeking damages for personal injuries suffered as a result of the Plaintiff's ingestion of a dangerous pharmaceutical

product "Actonel"¹ (risedronate sodium; hereinafter "Actonel"), which was continuously manufactured, marketed, advertised, and distributed to the general public by Defendants P&G and Aventis.

PARTIES

PLAINTIFF:

2. Plaintiff Joyce Luetticke was a citizen and resident of the State of Nebraska at the time the instant cause of action arose and is a citizen of the State of Nebraska at the time of filing this action. Plaintiff resides in Omaha, Douglas County, Nebraska.

DEFENDANTS

3. At all times mentioned, Defendant P&G was and is a corporation incorporated, operating and existing under the laws of incorporation of the State of Ohio, with its principal place of business at One Procter Gamble Plaza, Cincinnati, Ohio 45202.

4. At all times mentioned, Defendant Aventis was and is a corporation incorporated, operating and existing under the laws of incorporation of the State of Delaware, with its principal place of business at 200 Crossing Boulevard, Bridgewater, New Jersey 08807.

5. At all times herein mentioned, Defendants P&G and Aventis, in interstate commerce and in this judicial district, purposefully marketed, designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, and retailers for resale to physicians, hospitals, medical practitioners and the general public, a certain pharmaceutical product, hereinafter referred to as Actonel. At all times herein mentioned, the Defendants were the actors engaged in

¹ Actonel is the registered trademark of Defendants P&G and Aventis.

the acts herein alleged, acting through its agents and employees, and at all times, the actions and omissions asserted in this pleading were committed by agents or employees acting within the purpose and scope of said agency and/or employment, and/or all of said acts and conduct were ratified and approved by said Defendants.

JURISDICTION AND VENUE

6. Jurisdiction is proper in this court pursuant to 28 U.S.C. §1332 for the reason that there is complete diversity of citizenship between Plaintiff and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars (\$75,000.00) exclusive of interest and costs.

7. Venue is proper in this judicial district pursuant to Case Management Order No. 3.

SUMMARY OF THE CASE

8. P&G and Aventis, either directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and/or sold Actonel for the treatment of osteoporosis, prevention of bone loss, Paget's Disease, among other uses.

9. As a result of the defective nature of Actonel, persons who were prescribed and ingested Actonel, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including without limitation, one or more of the following: bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw.

10. P&G and Aventis concealed their knowledge of Actonel's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community. Defendants

P&G and Aventis failed to conduct adequate and sufficient post-marketing surveillance of Actonel after they began marketing, advertising, distributing, and selling the drug.

11. As a result of Defendants' actions and inaction, Plaintiff was injured due to ingestion of Actonel, which has caused and will continue to cause her various injuries and damages. Plaintiff accordingly seeks compensatory damages and other damages.

FACTUAL ALLEGATIONS

12. At all relevant times, Defendants P&G and Aventis were responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing and selling Actonel, as detailed below.

13. The United States Food and Drug Administration ("FDA") approved P&G and Aventis' compound Risedronate sodium for various uses, including the treatment of osteoporosis. Risedronate sodium is marketed by Defendants P&G and Aventis as Actonel.

14. Actonel falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's Disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

15. There are two classes of bisphosphonates: the N-containing (nitrogenous) and nonN-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and risedronate (Actonel). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid).

Risedronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for Actonel confirms that the molecule contains a nitrogen atom.

16. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion and inflammation of the upper gastrointestinal tract, P&G and Aventis knew or should have known that Actonel, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

17. P&G and Aventis also knew or should have known² that bisphosphonates, including Actonel, inhibit endothelial cell function. Similarly, P&G and Aventis knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

18. P&G and Aventis also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That, in turn, can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

19. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on Actonel.

² Throughout this Complaint, whenever Plaintiff asserts P&G and Aventis "should have known," Plaintiff is asserting that the dangerous propensity of Actonel was knowable to P&G and Aventis given the accepted scientific knowledge at the time of manufacture and distribution.

20. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

21. Shortly after Defendants began selling and distributing Actonel, reports of bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw and other dental complications among users began surfacing, indicating that Actonel shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, P&G and Aventis failed to implement further study of osteonecrosis and/or osteochemonecrosis of the jaw relative to Actonel.

22. Bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw is a serious medical event and can result in severe disability and death.

23. Rather than warn patients, and despite knowledge of an increased risk of bisphosphonate induced osteonecrosis and/or osteochemonecrosis of the jaw on patients using Actonel, P&G and Aventis continued to defend Actonel, mislead physicians and the public, and minimize unfavorable findings.

24. Consumers, including Plaintiff, who have used Actonel for the treatment of osteoporosis, have several alternative safer products available to treat the conditions.

25. P&G and Aventis knew of the significant risk of dental and oral complications caused by ingestion of Actonel, but did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.

26. P&G and Aventis aggressively marketed Actonel throughout the United States. This marketing was directed to consumers and medical professionals (including physicians and leading medical scholars).

27. As a direct result, Plaintiff was prescribed Actonel and has been permanently and severely injured, having suffered serious consequences from the ingestion of Actonel. Plaintiff requires and will in the future require on-going medical care and treatment.

28. Plaintiff has suffered from mental anguish from the knowledge that she will have life-long complications as a result of the injuries she sustained from the use of Actonel.

29. Plaintiff used Actonel as prescribed and in a foreseeable manner.

30. As a direct and proximate result of using Actonel, Plaintiff suffered severe bisphosphonate induced osteochemonecrosis and/or osteomyelitis of the jaw.

31. Plaintiff, as a direct and proximate result of using Actonel, suffered severe and physical pain and suffering and has sustained permanent injuries and emotional distress. Plaintiff's injuries and damages exceed the jurisdictional amount required by this Court.

32. Plaintiff used Actonel, which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

33. Based upon information and belief, the physician who supplied Actonel to Plaintiff reasonably relied on the representations made to him by P&G and Aventis prior to the date of prescribing Actonel for use. Based upon information and belief, the physician reasonably relied on the representations regarding the safety of Actonel and would have altered his prescription habits by considering alternative treatments, altering his informed consent, and/or would not have recommended Actonel if he had known the true facts regarding the safety of Actonel. Thus, based on information and belief, had

Plaintiff's physician known the true facts, the drug would not have been prescribed to Plaintiff because of one or more of the following: the physician would not have recommended Actonel to Plaintiff and would have prescribed an alternative product; Plaintiff would have used the information provided by the physician and chosen an alternative medicine. In either event, Defendants' failure to provide true and accurate information to Plaintiff's physician, by omission and/or commission, was the proximate cause of Plaintiff's injuries.

34. Plaintiff would not have used Actonel had P&G and Aventis properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

35. Prior to the dates upon which the aforesaid product was prescribed to Plaintiff, P&G and Aventis knew, or should have known, that Actonel was extremely dangerous and unsafe for use by the general public for the treatment and prevention of osteoporosis. Yet, P&G and Aventis, through their affirmative misrepresentations and omissions, failed to take appropriate action to cure the nature of the defects and actively concealed from Plaintiff and her physician the true and significant risks associated with taking Actonel. The running of any applicable statute of limitations has been tolled by reason of P&G and Aventis's fraudulent concealment.

36. As a result of Defendants' actions, Plaintiff and her prescribing physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that

those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

FIRST CAUSE OF ACTION
[Strict Products Liability Failure to Warn]

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 36, inclusive, of this Original Complaint, and for cause of action state that Defendants' conduct makes them strictly liable in tort for failure to adequately warn.

37. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing and/or promoting Actonel, and through that conduct have knowingly and intentionally placed Actonel into the stream of commerce with full knowledge that it would arrive in the judicial district where the Plaintiff ingested it. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Actonel to Plaintiff's pharmacy, Plaintiff's prescribing physician and ultimately, Plaintiff. Additionally, P&G and Aventis expected the Actonel they were selling, distributing and supplying, manufacturing and/or promoting to reach, and Actonel did in fact reach, prescribing physicians and consumers throughout the United States, including Plaintiff, and Plaintiff's prescribing physician, without substantial change in the condition of the product.

38. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture, and was so at the time it was distributed by Defendants and ingested by Plaintiff. Specifically, the Actonel ingested by Plaintiff was in a defective condition because Defendants distributed the product without adequate warning, failed to properly package the product and/or failed to label the product to give reasonable

warnings of danger about the product. Given the severity of the adverse effects of Actonel, the aforesaid product was defective in that it was not properly prepared and/or was not accompanied by proper warnings regarding all possible adverse side effects associated with the use of Actonel. Thus, P&G and Aventis failed to warn of a substantial danger not readily recognizable to an ordinary consumer, and the danger was known or knowable to P&G and Aventis given the accepted scientific knowledge at the time of manufacture and distribution. These defects caused serious injuries to the user when Actonel was used in its intended and foreseeable manner, i.e., when it was ingested as prescribed by Plaintiff's physician and in the manner recommended and/or marketed by Defendants.

39. P&G and Aventis knew that the aforesaid product was to be used by the user without inspection for defects therein, and that the Plaintiff was among the class of persons that might foreseeably be harmed by the product Actonel after its prescription, purchase and ingestion.

40. Plaintiff used the product for its intended purpose.

41. The aforesaid product was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the product, i.e., ingestion to aid in the treatment of osteoporosis, involved substantial dangers not readily recognizable by the ordinary, reasonably foreseeable user of the product. P&G and Aventis failed to warn of the known or knowable likelihood of injury including, but not limited to the likelihood the user would develop osteonecrosis and/or osteochemonecrosis.

42. Plaintiff did not know, nor did Plaintiff have reason to know, at the time of the use of the aforesaid product, or at any time prior thereto, of the existence of the foregoing described defects. These defects and/or the failure to warn of these defects caused the herein described injuries to Plaintiff and the injuries from which the Plaintiff continues to suffer.

43. P&G and Aventis knew that the aforesaid product was to be used by the user without inspection for defects therein and that the aforesaid product was unaccompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

44. Plaintiff neither knew, nor had reason to know, at the time of the use of the aforesaid product, or at any time prior thereto, of the existence of the foregoing described defects. Thus, P&G and Aventis' failure to adequately warn Plaintiff and/or Plaintiff's physicians proximately caused Plaintiff's injuries.

SECOND CAUSE OF ACTION
[Strict Products Liability/Defective Product]

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 44, inclusive, of this Original Complaint, and for cause of action state that Defendants P&G and Aventis' conduct creates strict liability in tort because the Actonel purchased and ingested by Plaintiff was a defective product.

45. Defendants P&G and Aventis have engaged in the business of selling, distributing, supplying, manufacturing, marketing and/or promoting Actonel, and through that conduct have knowingly and intentionally placed Actonel into the stream of commerce with full knowledge that it would arrive where Plaintiff purchased and ingested it. P&G and Aventis did in fact sell, distribute, supply, manufacture, and/or

promote Actonel to Plaintiff and Plaintiff's prescribing physician. Additionally, P&G and Aventis expected the Actonel they were selling, distributing and supplying, manufacturing and/or promoting to reach, and did in fact reach, prescribing physicians and consumers in Plaintiff's home state, including Plaintiff, and her prescribing physician, without substantial change in the condition of the product.

46. The Actonel manufactured and/or supplied by P&G and Aventis was placed into the stream of commerce in a defective condition in that the foreseeable risks exceeded the benefits associated with the design or formulation and/or that the Actonel was in a condition (a) that failed to perform as safely as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner, or (b) the risk of danger inherent in the design of Actonel outweighed the benefit of its design.

47. Alternatively, the Actonel manufactured and/or supplied by P&G and Aventis was defective in design or formulation in that when it was placed in the stream of commerce, it was more dangerous than an ordinary consumer would expect, and it was more dangerous than other forms of treatment.

48. The Actonel manufactured and/or supplied by P&G and Aventis was defective because P&G and Aventis knew or should have known that the product created a risk of harm to consumers and that P&G and Aventis failed to adequately warn of said risks.

49. The Actonel manufactured and/or supplied by Defendants P&G and Aventis was defective due to one or more of the following reasons:

- a. The product was not safe for ingestion as designed in that it caused permanent and/or progressive physical injury and other physical injuries;
- b. The product as designed and/or sold by P&G and Aventis did not properly protect users from harm;
- c. The product caused Plaintiff to be exposed to harmful substances;
- d. The product was not safe for its intended use;
- e. The product as designed and/or distributed did not properly address various safety issues;
- f. The product was not tested properly or adequately;
- g. The risk of product usage for known and/or intended uses was outweighed by the risk of usage;
- h. The product had an inadequate warning;
- i. P&G and Aventis failed their post-sale duty to warn of newly discovered harm;
- j. The product failed to perform as safely as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner;
- k. The risk of danger inherent in the design of Actonel outweighed the benefit of its design; and/or,
- l. The product was otherwise in a defective condition under applicable state law.

50. As designed, the Actonel contained dangerous design defects and was not reasonably safe as intended -- making the risks of Actonel outweigh its benefits and subjecting Plaintiff to risks which exceeded any alleged benefits of Actonel.

51. The Actonel manufactured and/or supplied by P&G and Aventis was defective due, *inter alia*, to inadequate post-marketing warning or instruction because after P&G and Aventis knew or should have known of the risk of injury from Actonel, they failed to provide adequate warnings to users or consumers of the product and continued to promote the product improperly.

52. Plaintiff used the product for its intended and/or reasonably expected usage or purpose.

53. As a proximate and legal result of the defective condition of this product manufactured and/or supplied by P&G and Aventis, Plaintiff was caused to suffer harm and the herein described injuries from which the Plaintiff continues to suffer. Thus, P&G and Aventis' conduct proximately caused Plaintiff's injuries.

THIRD CAUSE OF ACTION
[Negligence and Gross Negligence]

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 53, inclusive, of this Original Complaint.

54. At all times herein mentioned, P&G and Aventis had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings, and take such steps to assure that the product Actonel did not cause users to suffer from unreasonable and dangerous side effects. P&G and Aventis owed Plaintiff this duty. P&G and Aventis breached this duty by:

- a. failing to properly and thoroughly test Actonel before releasing the drug to market;
- b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Actonel;
- c. failing to conduct sufficient post-market testing and surveillance of Actonel;
- d. designing, manufacturing, marketing, advertising, distributing and selling Actonel to consumers, including Plaintiff, without adequate warning of the significant and dangerous risks of Actonel and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- e. failing to exercise due care when advertising and promoting Actonel; and
- f. negligently continuing to manufacture, market, advertise, and distribute Actonel after P&G and Aventis knew or should have known of its adverse effects without providing an adequate warning of the known or knowable side-effects of Actonel.

55. At all times herein mentioned, P&G and Aventis knew, or in the exercise of reasonable care should have known, that the aforesaid product was of such a nature that if it was not properly manufactured, compounded, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied and prepared and provided with proper warnings, it was likely to injure the product's user.

56. Defendants P&G and Aventis so negligently and carelessly manufactured, compounded, tested, failed to test, inspected, packaged, labeled, distributed,

recommended, displayed, sold, examined, failed to examine, and supplied the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

57. Defendants P&G and Aventis negligently failed to warn of the nature and scope of dangers associated with Actonel.

58. Defendants P&G and Aventis were aware of the probable consequences of the aforesaid conduct. Despite the fact that P&G and Aventis knew or should have known that Actonel caused serious injuries, they failed to disclose the known or knowable risks associated with the product as set forth above. Defendants P&G and Aventis willfully and deliberately failed to avoid those consequences, and in doing so, P&G and Aventis acted with a conscious disregard of the safety of Plaintiff and were therefore grossly negligent.

59. In all the above actions, P&G and Aventis had a duty to act as reasonable and prudent pharmaceutical manufacturers of a prescription drug, but breached this duty by failing to act as reasonable and prudent pharmaceutical manufacturers of a prescription drug, and by breaching the standard of care proximately caused the Plaintiff to suffer physical injuries and other damages. As a result of the carelessness, negligence and gross negligence of Defendants P&G and Aventis alleged herein and in such other ways to be later shown, the aforesaid product was a proximate cause of Plaintiff's injuries as herein alleged.

FOURTH CAUSE OF ACTION [Breach of Implied Warranty]

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 59, inclusive, of this Original Complaint.

60. At all times mentioned herein, P&G and Aventis manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold the aforesaid product, and prior to the time it was provided to Plaintiff, Defendants impliedly warranted to Plaintiff that the product was of merchantable quality and safe for the use for which it was intended.

61. Plaintiff reasonably relied on the skill and judgment of P&G and Aventis in using the aforesaid product.

62. The product was unsafe for its intended use and was not of merchantable quality, as warranted by Defendants in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. The aforesaid product was unaccompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a direct and proximate result of P&G and Aventis' breach of warranty, Plaintiff sustained damages as alleged herein.

63. The aforesaid product did cause Plaintiff to sustain injuries and damages as herein alleged.

64. After Plaintiff was made aware that Plaintiff's injuries were a result of the aforesaid product, notice was impractical due to the nature of the injuries and thus, the filing of suit gives notice.

FIFTH CAUSE OF ACTION
[Breach of Express Warranty]

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 64, inclusive, of this Original Complaint.

65. The aforementioned manufacturing, compounding, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of the aforesaid product was expressly warranted to be safe for use by Plaintiff and other members of the general public.

66. Defendants P&G and Aventis expressly warranted that Actonel was safe. Upon information and belief, these warranties were included in numerous advertisements to the public, documents prepared for physicians, documents prepared for the public and were also spoken directly to physicians by agents of Defendants P&G and Aventis. Upon information and belief, Defendants P&G and Aventis knew or reasonably should have known that consumers would have directly reasonably relied on these representations and/or that consumers would have indirectly reasonably relied on these representations in that their physicians would reasonably rely on these representations, and that consumers would rely on the prescription advice of their physicians acting as either their agent, fiduciary or intermediary and who were directly acting based on these fraudulent representations.

67. Actonel failed to conform to the Defendants' warranties because Actonel was not safe.

68. At the time of the making of the express warranties, Defendants P&G and Aventis had knowledge of the purpose for which the aforesaid product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The aforesaid product was unaccompanied by warnings of its dangerous propensities that were either known or knowable at the time of distribution.

69. Upon information and belief, Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants P&G and Aventis, and upon said express warranty, in using the aforesaid product. The warranty and representations were untrue in that the product caused severe injury to Plaintiff and was unsafe and, therefore, unsuited for the use for which it was intended. The aforesaid product could and did thereby cause Plaintiff to sustain injuries and damages as herein alleged.

70. As soon as the true nature of the product, and the fact that the warranty and representations were false, were ascertained, notice was impractical due to the nature of the injuries and thus, the filing of suit gives notice to P&G and Aventis of the breach of said warranty.

71. As a direct and proximate result of the breach of these warranties, Plaintiff sustained personal injuries and other damages as alleged herein.

SIXTH CAUSE OF ACTION [Fraud]

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 71, inclusive, of this Original Complaint.

72. Defendants P&G and Aventis falsely and fraudulently represented to Plaintiff, Plaintiff's physicians and members of the general public, that the aforesaid product was safe for use to aid in treating osteoporosis and was safer than other readily available treatments. The representations by P&G and Aventis were, in fact, false. The true facts, include, but are not limited to, the fact that the aforesaid product was not safe for said purpose and was, in fact, dangerous to the health and body of Plaintiff.

73. Furthermore, Actonel was not adequately tested and there were frequent, severe, protracted, debilitating, difficult, life threatening and disabling side effects and

adverse effects of the product, including, but not limited to, osteonecrosis and/or osteochemonecrosis of the jaw. Defendants did not disclose or warn Plaintiff or Plaintiff's physicians about the known risk of injury in using the product. Defendants misrepresented the safety of the product, represented that the product marketed was safe for treating osteoporosis, and concealed warnings of the known or knowable risks of injury in using the product.

74. When Defendants P&G and Aventis made these representations -- about material facts - they knew that they were false. Defendants made said representations with the intent to defraud and deceive Plaintiff and with the intent to induce Plaintiff to act in the manner herein alleged. Upon information and belief, Defendants P&G and Aventis knew or reasonably should have known that consumers would have directly reasonably relied on these representations and/or that consumers would have indirectly reasonably relied on these representations in that their physicians would reasonably rely on these representations, and that consumers would rely on the prescription advice of their physicians acting as either their agent, fiduciary or intermediary and who were directly acting based on these fraudulent representations.

75. At the time P&G and Aventis made the aforesaid representations, and at the time Plaintiff took the actions alleged herein, upon information and belief, Plaintiff and Plaintiff's physicians were ignorant of the falsity of these representations, reasonably believed them to be true, and relied upon them. Upon information and belief, in reliance upon said representations, Plaintiff was induced to, and did, use the aforesaid product as herein described. Plaintiff's reasonable reliance on the deceptive statements resulted in Plaintiff's injuries.

76. If Plaintiff had known the actual facts, Plaintiff would not have taken such action.

77. The reliance of Plaintiff and Plaintiff's physicians on Defendants P&G and Aventis' representations was justified and reasonable because said representations were made by individuals and entities that appeared to be in a position to know the true facts.

78. As a result of P&G and Aventis' fraud and deceit, Plaintiff sustained the herein described injuries.

**SEVENTH CAUSE OF ACTION
[Fraud by Concealment]**

Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation in paragraphs 1 through 78, inclusive, of this Original Complaint, and for cause of action alleges as follows:

79. At all times mentioned herein, Defendants P&G and Aventis had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians, the true facts concerning the aforesaid product, specifically that said product was dangerous and defective and how likely it was to cause serious consequences to users, including injuries and death, and how unnecessary it was to use said product for the purposes indicated when considering alternative methods of treatment. Defendants made affirmative representations as set forth herein to Plaintiff, Plaintiff's physicians and the general public prior to the date Actonel was provided to Plaintiff, while concealing material facts mentioned herein.

80. At all times mentioned herein, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the aforesaid

product; that is, that use would cause injuries including but not limited to osteonecrosis and/or osteochemonecrosis.

81. At all times herein mentioned, Defendants P&G and Aventis intentionally, willfully and maliciously concealed or suppressed the facts set forth herein from Plaintiff and Plaintiff's physicians with the intent to defraud as herein alleged.

82. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not have used the product.

83. As a result of the concealment or suppression of the facts set forth above, Plaintiff suffered injuries as set forth herein.

84. That at all times herein mentioned, Defendants intentionally and willfully concealed or suppressed the facts set forth herein from Plaintiff's physicians and therefore from Plaintiff, with the intent to defraud Plaintiff as herein alleged.

85. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, Plaintiff would not have ingested Actonel.

86. As a proximate result of the concealment or suppression of the facts set forth above, Plaintiff suffered injuries as set forth herein.

PUNITIVE AND/OR EXEMPLARY DAMAGES

87. Clear and convincing evidence exists that the above described actions of Defendants P&G and Aventis were committed oppressively, fraudulently or with malice or oppression. The wrongful conduct for which Plaintiff seeks punitive damages was committed knowingly and/or authorized or ratified by an officer, director or managing

agent of the Corporations. Therefore, Plaintiff specifically requests that the Court submit jury questions on issues of Defendants P&G and Aventis' conduct to support punitive and/or exemplary damages in the maximum amount allowed by law.

COMPENSATORY DAMAGES

88. As a direct and proximate result of the actions of P&G and Aventis, Plaintiff has suffered the following damages in excess of the jurisdictional requirements of this court:

- a. Medical expenses incurred in the past and those reasonable and necessary expenses to be incurred in the future;
- b. Physical pain and suffering endured in the past and that likely to be suffered in the future;
- c. Mental anguish and emotional distress suffered in the past and that likely to be suffered in the future;
- d. Physical impairment suffered in the past and that likely to be suffered in the future;
- e. Disfigurement, past and future;
- f. Purchase costs;
- g. Such other damages to which Plaintiff is entitled in law or equity.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief from Defendants as follows:

89. In support of said damages, Plaintiff incorporates by reference all preceding and following paragraphs as if fully set forth herein and further alleges as follows:

- a) For general damages in a sum in excess of the jurisdictional minimum of this Court;
- b) For special damages in a sum in excess of the jurisdictional minimum of this Court;
- c) For compensatory damages in excess of the jurisdictional minimum of this Court;
- d) For consequential damages in excess of the jurisdictional minimum of this Court, according to proof;
- e) Medical, incidental, and hospital expenses according to proof;
- f) Future medical, incidental and hospital expenses according to proof;
- g) Prejudgment and post judgment interest as provided by law;
- h) Full refund of all purchase costs Plaintiff paid for Actonel;
- i) Punitive damages;
- j) Attorneys' fees, expenses and costs of this action; and
- k) Such further relief as this Court deems necessary, just and proper

DEMAND FOR JURY TRIAL

90. Plaintiff demands a jury trial in this action.

DATED: 1/22/08

Respectfully submitted,

By: Alexandra V. Boone
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